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EXAMINER	
SWEET, THOMAS	

ART UNIT	PAPER NUMBER
3738	

DATE MAILED: 04/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/056,774	HOLMBERG ET AL.	
	Examiner	Art Unit	
	Thomas J Sweet	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 March 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 39-49 and 51 have been considered but are moot in view of the new ground(s) of rejection.

The arguments with regard to "band" are also moot, since in the broadest reasonable interpretation of the term band as dictionary defined is structurally inadequate to support novelty over the prior art of record which include reinforcement elements that can be characterized as bands.

The arguments with regard to "limits dilation" are also moot, since any reinforcement would inherently present a stiffer area then the base material (biocompatible material) surrounding the reinforcement and therefore would limit dilation as compared to the base material.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 39 is rejected under 35 U.S.C. 102(b) as being anticipated by Duran (US 5545215). Duran discloses a prosthesis (fig 9) comprising a reinforcement element (20, which can be characterized as a band) and a prosthetic conduit (28) of biocompatible material having a

cylindrical section effectively ending in an expanded section with the reinforcement element at least a portion of which is positioned circumferentially at the junction there between and a portion of the reinforcement element 20 is attached proximate to where the conduit ends (one end) and the valve begins but is still downstream from the valve and inherently limits dilation based on its stiffness.

Claims 42, 44 and 51 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Klostermeyer et al (US 5891195). See figure 3.

With regards to claim 51, Klostermeyer et al discloses a prosthesis (figure 3) comprising a reinforcement element (52 which can be characterized as a band and inherently limits dilation based on its stiffness and by entrapping the conduit between members 44 and 20) and a prosthetic conduit (12) comprising biocompatible material, the prosthetic conduit having only a single generally cylindrical section (12) and an expanded section (14 including 36) extending from an end of the generally cylindrical section, wherein the reinforcement element (52) is circumferentially positioned at the junction between the generally cylindrical section and the expanded section.

Claim 48 is rejected under 35 U.S.C. 102(b) as being anticipated by Fogarty et al. Fogarty et al discloses a prosthesis (fig. 3) comprising a reinforcement element (as seen in figs. 3A-D) and a prosthetic conduit comprising biocompatible material, wherein the reinforcement element comprises a band circumferentially attached (any of figs. 3A-D can be characterized as having a band 84/85) to the prosthetic conduit proximate to the outflow edge to limit dilation.

Claims 1, 7-15, 18, 27-29, 36, 38, 40 and 50 are rejected under 35 U.S.C. 102(a) as being anticipated by De Paulis (US 2001/0049553). De Paulis discloses a prosthesis (fig. 2) comprising

a reinforcement element (26) and a prosthetic conduit comprising biocompatible material ([0037]), the prosthetic conduit having a generally cylindrical section (12) and an expanded section (14) extending from an end (at 28) of the generally cylindrical section (12) and terminating at an edge (also at 28), wherein the reinforcement element (26) is circumferentially positioned (connection 28) at the junction between the generally cylindrical section and the expanded section.

With regard to claims 7-8, the biocompatible material comprises at least two segments joined form the conduit ([0017]). One segment forms the generally cylindrical section and portion of the expanded section (fig. 2).

With regard to claim 9, the biocompatible material comprises a single segment (see the embodiment of figs. 3 and 4).

With regard to claims 10 and 11, the expanded section has a maximum diameter from about 12% to about 20% larger than the average diameter of the generally cylindrical section ([0002]).

With regard to claims 12 and 36, the expanded section has scallops along its free edge for attachment around a native aortic heart valve ([0059]).

With regard to claims 13 and 38, prosthetic valve connected to the expanded section ([0019]).

With regard to claim 14, the prosthetic rigid leaflet connected to an orifice ring (see the embodiment of fig. 5)

With regard to claim 15, the prosthetic valve (i.e. reimplanted after modification) comprises tissue leaflets (see the embodiment of fig. 6).

With regard to claim 18, the expanded section has two components (14 and the valve) that connect together to complete the formation of the expanded section

With regard to claim 27, the reinforcement element surrounds only portion of the circumference the biocompatible material (the suture 26 stitches in and out around the circumference).

With regard to claims 28 and 29, the prosthetic conduit has a reinforcement near the inflow edge and has a reinforcement near the outflow edge (sutured in place when implanted.

With regard to claim 40, The connection (28) using reinforcement element (suture 26) inherently inhibit dilation of the conduit since a sutured double layered seam is stiffer than the biocompatible material.

With regard to claim 50, the prosthesis comprising a reinforcement element (suture), a prosthetic conduit comprising biocompatible material and a prosthetic valve circumferentially attached to the prosthetic conduit, wherein the reinforcement element (suture) is attached the prosthetic conduit proximate to the inflow edge (see the embodiment of fig. 5 in which the valve is sutured in place).

Claims 1, 7, 8, 18, 19, 26-29 and 48 are rejected under 35 U.S.C. 102(a) as being anticipated by Solem (US 2001/0041927). Solem discloses a prosthesis (fig. 3) comprising a reinforcement element (15 or 16) and a prosthetic conduit comprising biocompatible material, the prosthetic conduit having a generally cylindrical section (6) and an expanded section (13) extending from an end of the generally cylindrical section (6) and terminating at an edge (near 15

best seen in fig. 5), wherein the reinforcement element (15 or 16) is circumferentially positioned at the junction between the generally cylindrical section and the expanded section.

With regard to claim 26, the reinforcement element surrounds the circumference of the biocompatible material (in the case of element 15 being the reinforcement).

With regard to claim 27, the reinforcement element surrounds only portion of the circumference the biocompatible material (in the case of element 16 being the reinforcement).

With regard to claim 28,the prosthetic conduit has a reinforcement near the inflow edge (stent 10 constitutes a reinforcement at the inflow edge).

With regard to claims 29 and 48, the prosthetic conduit has a reinforcement band (sleeve, ring) near the outflow edge (there are corresponding connectors as seen in figure 3 at both ends of the bypass member 6).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 21-22 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over De Paulis. De Paulis discloses a prosthesis as discussed above. However, De Paulis does not specify that the reinforcement element (suture) is made of polymer. It is well known in the art of suture to make them of polymer materials for the purpose of being biocompatible. It would have been obvious to one of ordinary skill in the art at the time

the invention was made to make the suture (reinforcement element) out of a polymer material in order for it to be biocompatible.

With regard to claim 22, the polymer is woven (stitched) into a fabric.

Claims 10, 11, 21 and 23 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Solem. Solem discloses a prosthesis as discussed above.

With regard to claims 10-11, although Solem does not specify any size relationship between the expand and cylindrical sections, it is within the scope of the invention to vary the size to accommodate the anatomy of a particular patient. It would have been obvious to one of ordinary skill in the art at the time the invention was made to vary the size relationship between the expand and cylindrical sections such that the expanded section has a maximum diameter from about 12% to about 20% larger than the average diameter of the generally cylindrical section in order to accommodate the anatomy of a particular patient.

With regard to claims 21 and 23, although Solem does not specify the material of the reinforcement element (15 and 16), it is well known in the art of prosthetic to uses various polymer (such as polyurethane) and metals (such as Nitinol) for components of prosthetics for the purpose of being biocompatible. It would have been obvious to one of ordinary skill in the art at the time the invention was made use a polymer or metal (such as polyurethane and Nitinol) to make the reinforcement element (15 and 16) of Solem in order to be biocompatible.

Claims 2-6, 16, 20, 24, 25 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over De Paulis. De Paulis discloses a prosthesis as discussed above. However, De

Paulis remains silent as to the use of tissue (including pericardium, submucosa, dura mater, ovine, equine, bovine and glutaraldehyde crosslinked tissues) as the biocompatible material even though " any suitable biocompatible material" is specified ([0037]). It is well known in the art of prosthetics to use tissue (including pericardium, submucosa, dura mater, ovine, equine, bovine and glutaraldehyde crosslinked tissues) in a prosthetic for the purpose of being biocompatible. It would have been obvious to one of ordinary skill in the art at the time the invention was made use a tissue (including pericardium, submucosa, dura mater, ovine, equine, bovine and glutaraldehyde crosslinked tissues) to make the prosthetic of De Paulis in order to be biocompatible.

With regard to claim 16, De Paulis does not disclose the use of flexible polymer leaflets in the prosthetic valve. It is well known in the art of prosthetic valves to use flexible polymer leaflets as the valve element for the purpose of mimicking the natural heart valve. It would have been obvious to one of ordinary skill in the art at the time the invention was made utilize a prosthetic valves comprising flexible polymer leaflets as a substitute for a natural heart valve and such a modification amounts to mere substitution of one functional equivalent heart valve for another in the art of prosthetic valves.

With regard to claims 20 and 24-25. The prosthesis as modified using tissue (pericardium) can be characterized as using tissue for the reinforcement element, since connection (28) would include a seam of two layers of tissue bound by suture which amounts to a roll or band of tissue (pericardium).

Claims 17 and 30-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over De Paulis in view of Ramos Martinez (5314468). De Paulis discloses a prosthesis as discussed

above. However, De Paulis does not disclose the use of tubules positioned for the attachment of the right and left coronary arteries. Ramos Martinez teaches another prosthesis including tubules positioned for the purpose attachment of the right and left coronary arteries as in the natural structure. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the prosthesis of De Paulis to include tubules positioned as taught by Ramos Martinez in order to attachment of the right and left coronary arteries as in the natural structure.

With regard to claim 34, De Paulis discloses the use of a modified natural heart which is stentless with flexible leaflets and leaflet support structure as modified by Ramos Martinez is positioned to avoid blockage the tubules.

With regard to claim 35, De Paulis remains silent as to the use of tissue as the biocompatible material even though " any suitable biocompatible material" is specified ([0037]). It is well known in the art of prosthetics to use tissue in a prosthetic for the purpose of being biocompatible. It would have been obvious to one of ordinary skill in the art at the time the invention was made use a tissue to make the prosthetic of De Paulis in order to be biocompatible.

Claims 19, 39, 41-47, 49 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over De Paulis in view of Solem. De Paulis discloses a prosthesis as discussed above. However, De Paulis does not disclose the use of a ring/band for the reinforcement element for connecting the sections. Solem teaches another prosthesis including a ring/band reinforcement element (sleeve 15 and 16) for the purpose of connecting sections of prosthesis. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the prosthesis of De Paulis to include a ring/band reinforcement element as taught by

Solem in order to connect sections of the prosthesis and such a modification amounts to mere substitution of one functionally equivalent connector for another in the art of prosthetics.

With regard to claim 41, the prosthetic conduit has a reinforcement near the inflow edge and has a reinforcement near the outflow edge (sutured in place when implanted).

With regard to claim 45, the expanded section has generally spherical shape over a portion of a sphere (14).

With regard to claim 46, the prosthetic valve has flexible leaflets (see fig. 6).

With regard to claim 47, the expanded section with three lobes (as seen in fig. 6 between commissures of the modified natural heart valve).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. De Paulis (US 6,352,554).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas J Sweet whose telephone number is 571-272-4761. The examiner can normally be reached on 6:30 am - 5:00pm, M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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